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Original article

Broncalt®, class II medical device, in patients with chronic relapsed upper airways disease: a survey in clinical practice

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Summary. Chronic respiratory otorhinolaryngological (ORL) diseases may exacerbate. Broncalt® is a class II Medical Device containing: thermal water (Medesano, PR, Italy), hyaluronic acid, and grapefruit seed extract. It could exert a safe and effective anti-inflammatory, washing, and antimicrobial activity. The current survey, conducted in clinical practice of 84 Italian ORL centers, evaluated its safety and efficacy in the treatment of patients with exacerbated chronic upper airways disease. The 459 (254 males, mean age 44.7 years) patients were evaluated at baseline (T0) and after a 2-week treatment (T1), treated or not-treated with Broncalt®. Signs and symptoms severity were measured by visual analogue scale. Broncalt® significantly, quickly, and safely diminished the clinical features in all sub-groups ($p<0.001$ for all). In conclusion, Broncalt® is a class II Medical Device able to exert a safe, quick, and effective activity in patients with relapsed chronic ORL disorders. (www.actabiomedica.it)

Key words: upper airways, exacerbated chronic disease, thermal water, hyaluronic acid, grapefruit seed extract

Introduction

Airways disorders are very common in clinical otorhinolaryngological (ORL) practice. Chronic upper airways diseases may relapse usually because of infections.

Respiratory exacerbations may be commonly caused by bacterial, viral or fungal aetiology, even though non-infectious cause might also be implied. However, infection is the most frequent reason for exacerbated chronic ORL disease. The treatment of relapsed chronic airways diseases is targeted to fight

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both infection and inflammation using antibiotics and anti-inflammatory drugs. Pharmacological therapy is usually effective, but there is increasing interest to consider complementary medicine as alternative option (1-3).

In this regard, Broncalt® is a new class II medical device containing salso-bromo-iodine thermal water (spring of Medesano, PR, Italy) 8%, hyaluronic acid (HA) 0.1%, and grapefruit seed extract 0.35%.

Recently, it has been reported that Broncalt® was effective in the treatment of postnasal drip-related cough in children with upper respiratory tract infections (4).

On the basis of this background, an Italian survey explored the pragmatic approach of a group of otolaryngologists in the management of relapsed chronic upper-airways disorders in clinical practice. Therefore, the aim of the current survey was to evaluate the efficacy and safety of Broncalt® in outpatients with exacerbated chronic respiratory ORL diseases.

Materials and Methods

The current survey was conducted in 84 Italian ORL centers, distributed in the whole Italy, so assuring a wide and complete national coverage. Otolaryngologists were asked to recruit all consecutive patients visited because of exacerbated chronic ORL disease.

Patients were consecutively recruited during the specialist visit. The inclusion criteria were: to have a diagnosis of relapse of chronic ORL disease, both genders, and adulthood. Exclusion criteria were to have comorbidities and concomitant medications able to interfere the evaluation of outcomes. As this survey was based on a real-world practice, the doctors had the complete liberty of choosing the preferred medications on the basis of the best practice. Actually, patients were subdivided in 2 sub-groups: i) patients treated with standard therapy plus Broncalt® (active group), and ii) patients treated with standard therapy alone (control group).

All patients signed an informed consent. All the procedures were conducted in a real-world setting.

The treatment course lasted 2 weeks. The medical device Broncalt® (Aurora Biofarma, Milan, Italy) was taken following the specific indications, such as two tablets/daily. Patients were visited at baseline (T0), after 1-week treatment (T1), and after 2-week treatment (T2).

Clinical examination and fiber-endoscopy were evaluated in all patients at all visits.

All clinical data were inserted in an internet-platform that guaranteed the patients' anonymity and the findings' recording accuracy.

The following clinical parameters were evaluated: nasal obstruction, mucosal edema, hyperemia, earache, swelling, sore throat, dysphagia, dysphonia, and cough. These issues were considered both as the quote of patients having them and their perceived severity. Symptom severity was assessed by a visual analogue scale (VAS). VAS is a psychometric test widely used to measure the patient's perception of symptom severity, emotions, pain, etc. Currently, VAS is a reliable and valid tool to assess the perception of symptoms and signs (16). The VAS consisted of one ruler asking for signs and symptoms severity perception. In this study, the VAS was a 10-cm horizontal line on which 0 implied the absence of sing or symptom, while 10 corresponded to maximal severity. VAS is considered a routine and validated parameter to assess disease severity in clinical practice and inflammatory markers are closely related with nasal obstruction perception (17).

In addition, the symptom disappearance duration was also considered, such as 3 period were established for symptom receding: by 3 days, between 4-7 days, and beyond 7 days.

Doctors also evaluated: the effectiveness (scored as very effective, effective, scarcely effective, and ineffective), the tolerability (scored as very good, quite good, poorly good, no good), and the compliance (very good, good, scarcely good, and no good).

Safety was measured by reporting the occurrence of adverse events.

The paired T-test was used. Statistical significance was set at $p < 0.05$. Data are expressed as medians and 1th and 3rd quartiles. The analysis was performed using STATA, College Station, Texas, USA.

Results

Globally, 459 (254 males, mean age 44.7 years) patients were visited and completed the treatment course.

The demographic characteristics and type of chronic respiratory disease are reported in Table 1.

In particular, the two subgroups were similar concerning the gender and the age.

The distribution of chronic relapsed respiratory diseases was significantly different about some types, i.e. patients not-treated with Broncalt had more frequently recurrent otitis an chronic tonsillitis, whereas Broncalt-treated patients suffered more commonly from chronic pharyngitis. Subgroup treated with Broncalt took significantly less antibiotics, but more anti-inflammatory drugs than the other subgroup; interestingly Broncalt-treated subgroups did not take any medication more frequently (51% versus 6.3%).

Considering the frequency of patients without symptoms or signs after the treatment, Broncalt treatment induced higher percentages of symptomless patients for nasal obstruction, rhinorrhea, dysphonia, and edema (Table 2).

The percentages of patients treated with or without Broncalt with global symptom disappearance within 3 days, and over 7 days were significantly different between groups (Figure 1). In particular, 44.7% of Broncalt-treated patients and 14.3% of patients without Broncalt treatment had no more symptoms within 3 days (p=0.007). On the contrary, 27% of patients without Broncalt treatment and 66.7% of Broncalt-treated patients still present symptoms over one week (p<0.001).

In patients treated with Broncalt, the perception of efficacy was very good in 74.2% and good in 21.2% (Figure 2A); the tolerability was very good in 83.7% and good in 15.2% (Figure 2B); the compliance was very good in 82.6% and good in 16.3% (Figure 2C).

The treatment was well tolerated by all patients and no relevant adverse event was reported.

Table 1. Demographic and clinical characteristics of patients, treated with or without Borncalt

	Broncalt N=396		No Broncalt N=63		p-value
Characteristic					
Male gender, n(%)	223	56.3%	31	49.2%	0.292
Mean age, (SD)	44.5	22.2	45.5	19.2	0.960
Relapsed disease					
Recurrent Otitis, n(%)	74	18.7%	8	12.7%	0.249
Chronic Tonsillitis, n(%)	**17**	**4.3%**	**9**	**14.3%**	**0.001**
Chronic Laryngitis, n(%)	40	10.1%	5	7.9%	0.592
Chronic Rhinopharyngitis, n(%)	112	28.3%	14	22.2%	0.317
Chronic Pharyngitis, n(%)	74	18.7%	13	20.6%	0.714
Dysphonia, n(%)	51	12.9%	8	12.7%	0.968
Concomitant treatments					
Antibiotics	**26**	**6.6%**	**5**	**7.9%**	
Cefalosporins	13	3.3%	3	4.8%	
Chinolones	4	1.0%	0	0%	
Macrolides	3	0.8%	0	0%	
Other	6	1.5%	2	1.1%	
Anti-inflammatory	**115**	**29.0%**	**23**	**3.2%**	
Antipyretics	3	0.8%	0	0%	
Corticosteroids	95	24.0%	18	28.6%	
FANS	10	1.3%	4	6.3%	
Other	7	2.5%	1	1.6%	
Anti-inflammatory+antibiotics	**53**	**13.4%**	**31**	**49.2%**	
No drug	**202**	**51.0%**	**4**	**6.3%**	

Table 2. Proportion of patients without symptoms and signs after treatment in the two subgroups: treated with or without Broncalt, evaluated at T1

Symptom	Broncalt	No Broncalt	P
Facial pain	21.2%	11.1%	0.062
Nasal Obstruction	**51.8%**	**31.8%**	**0.003**
Rhinorrea	**39.7%**	**22.2%**	**0.008**
Post nasal drip	30.8%	25.4%	0.384
Earache	21.7%	15.9%	0.289
Nose swelling	34.9%	30.2%	0.466
Sore thorat	23.7%	27.0%	0.576
Dysphonia	**25.8%**	**14.3%**	**0.048**
Cough	39.4%	27.0%	0.059
Hyperaemia	59.1%	47.6%	0.087
Edema	**41.2%**	**20.6%**	**0.002**

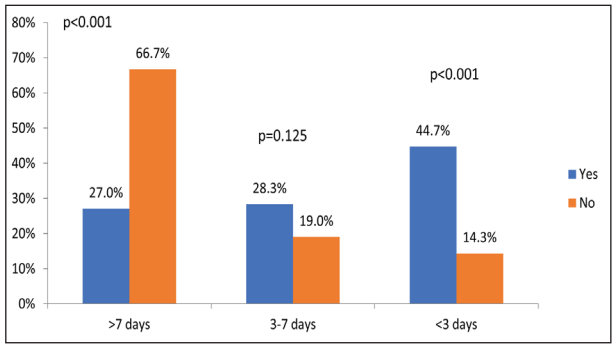

Figure 1. Percentages of patients treated with or without Broncalt with symptom disappearance within 3 days, between 3 and 7 days, and over 7 days.

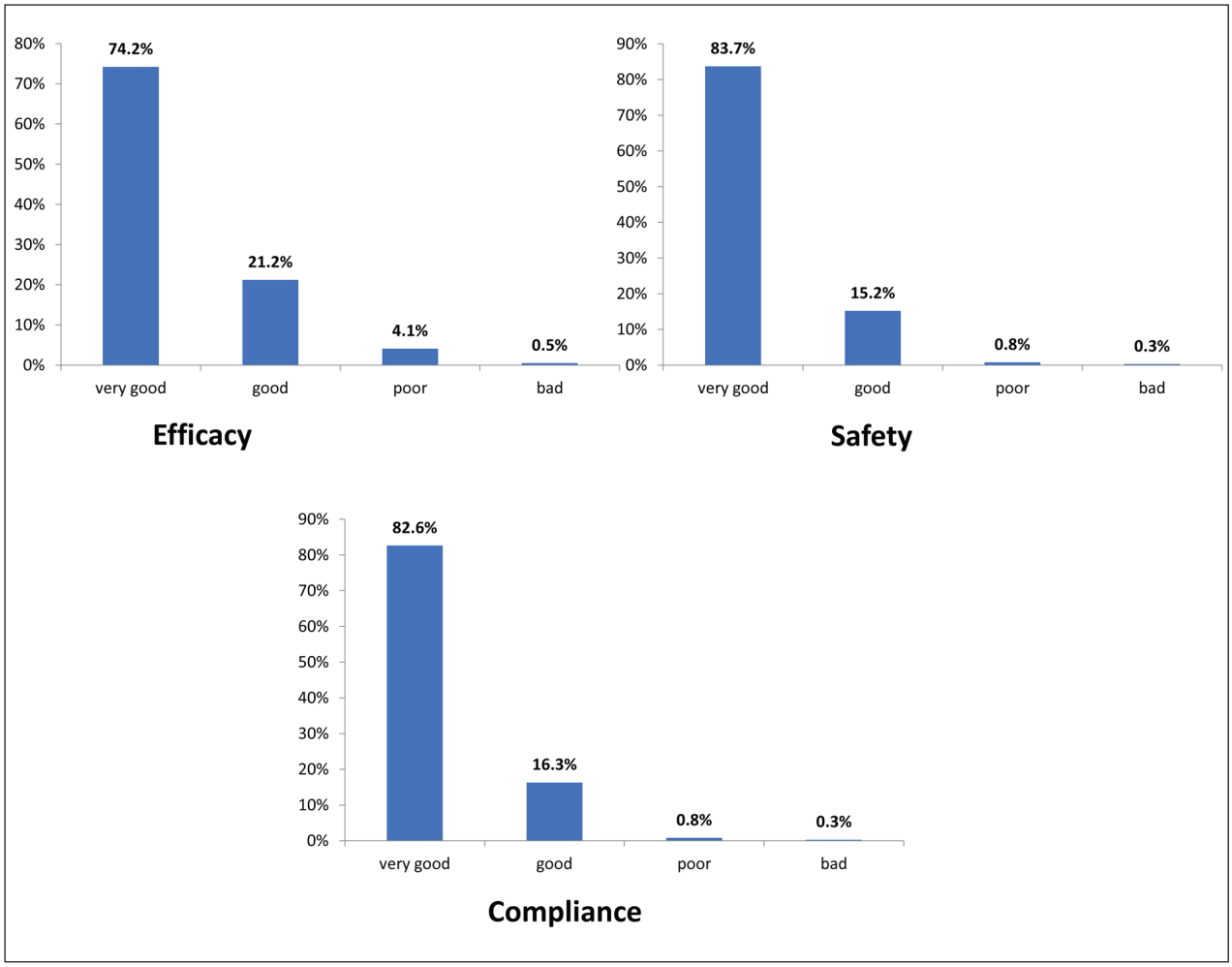

Figure 2. A= Patients' perception of Broncalt efficacy; B= Patients' perception of Broncalt tolerability; C= Patients' perception of Broncalt Compliance.

Discussion

The current survey demonstrated that Broncalt® significantly improved the clinical feature in relapsed chronic upper airways disorders in ORL clinical practice. In particular, the clinical effectiveness of Broncalt was quick as about 50% of treated patients achieved a symptom disappearance just within 3 days. Notably, patients in Broncalt subgroup more frequently did not assume any medication. The present findings are consistent with a previous study that explored the therapeutic effects of this medical device in the treatment of children with ORL infections (4).

The use of non-pharmacological treatment represents a challenging option. The present survey supports the concept that complementary medicine may have a role in clinical practice also in patients with respiratory exacerbation. In fact, previous systematic reviews evidenced that herbal medicines could be beneficial in the treatment of rhinosinusitis and othe ORL disorders (1-3). Therefore, the present survey confirms that a medical device, such as Broncalt®, may significantly reduce clinical features in chronic ORL disorders characterized by an exacerbation.

However, the current experience has some limitations, mainly concerning the open design and the lack of objective functional data. On the other hand, the strength of this survey is the high number of enrolled patients and the real-world setting, so the findings may mirror what occurs in the daily practice.

In conclusion, the present survey evidenced that Broncalt® may induce a safe and quick control of respiratory complaints in inflammatory exacerbated chronic ORL disorders.

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